REMARKS

This is submitted in response to the Office Action dated August 5, 2009, the Applicant submits the following remarks.

At the outset, it is noted that the claims of the present case as amended in the Preliminary Amendment dated August 18, 2006, were renumbered inappropriately, so the claims as amended herein include an attempt to rectify this discrepancy with respect to the claims as originally filed. Guidance for the new (original) numbering is provided. Claims 11-13, 27-31, and 35 were cancelled as of the filing of the preliminary amendment, and claims 1-10, 15-26, and 32-34 are amended herein to improve their readability and to better conform the claims to U.S. practice. Accordingly, claims 1-10, 14-26, and 32-34 are pending. Reconsideration and favorable action are respectively requested in light of the above amendments and the following remarks.

In the Office Action, the Examiner issued a requirement that Applicant make an election between what the Examiner says are the Group I claims (Claims 1-10), the Group II claims (Claims 11-22)[1], the Group III claims (Claims 11 and 23)[2], the Group IV claims (Claim 24)[3], the Group V claims (Claims 11 and 25)[4], and the Group VI claims (Claim 26)[5]. Without acknowledging the propriety of this grouping or any part of the Action, Applicant hereby provisionally elects Group I but this election is made with traverse and is solely for the purpose of advancing prosecution of this case. The requirement to restrict the invention is not well taken. Among other things, the claims are so sufficiently related that their respective classes would be thoroughly cross-referenced, and many of the same classes would be searched regardless of which group of claims was elected. There would be no substantial or undue search or examination burden if all these closely related claims were searched and examined in one application proceeding.

The Group I claims are directed to a process for preparing a stable granulate for reconstitution with water into an oral aqueous suspension comprising amoxicillin trihydrate and a sugar. The Group II claims are directed to a granulate comprising amoxicillin trihydrate and

[1] Using the original numbering scheme, these claims are 14-25.
[2] Using the original numbering scheme, these claims are 14 and 26, respectively.
[3] Using the original numbering scheme, these claims are 14 and 32, respectively.
[4] Using the original numbering scheme, these claims are 14 and 33, respectively.
[5] Using the original numbering scheme, these claims are 14 and 34, respectively.

a sugar. The Group III claims are directed to the granulate according to claim 14 (of the allegedly distinct Group II claims), wherein the granulate contains no pharmaceutically acceptable excipient. The Group IV claims are directed to an aqueous suspension including amoxicillin trihydrate and the sugar obtained after reconstitution of the granulate described in claim 1. The Group V claims are directed to a sachet product containing free flowing granulate as described in claim 14, which comprises amoxicillin trihydrate and the sugar in a suitable unit dose, for reconstitution with water into an aqueous suspension immediately prior to use. The Group VI claims are directed to a method of treatment of bacterial infections in humans or animals, which comprises the administration of a granulate comprising a therapeutically effective amount of amoxicillin trihydrate and a sugar. All sets of claims include a stable form of the granulate.

Thus, examination of the Group I claims will require a search/study of substantially the same prior art as will search and examination of the Group II claims, Group III claims, the Group IV claims, the Group V claims, and the Group VI claims. Each would require searching and study of all of the relevant art relating to the stable granulate comprising amoxicillin trihydrate and a sugar. It is therefore a more efficient use of Patent Office manpower and resources to examine all claims which are closely related at one time rather than conducting separate examinations.

Also, the mere fact that one group of claims is directed to a method and another group is directed to a composition does not mean a patent cannot be issued containing both groups of claims. Patents are routinely issued containing groups of method and apparatus or method and product claims.

Moreover, restriction is not "required" by 35 U.S.C. §121 as suggested by the Examiner. Congress wisely gave the Commissioner the "discretion" to require restriction. According to 35 U.S.C. § 121 "... the Commissioner may require the application to be restricted...." (emphasis added). Likewise, the MPEP § 803 lists two criteria that must be present for restriction to be proper:

1) The invention must be independent or distinct; and
2) There must be a serious burden on the Examiner if restriction is not required (emphasis added).

Because the Examiner has not shown any serious burden if examination of all the claims is conducted and the claims cover closely related subject matter, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement and examine all of the pending claims.

In the event this response is not timely filed, Applicant hereby petitions for the appropriate extension of time and requests that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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